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The Obesity Paradox in Patients with Diabetes Mellitus after Percutaneous Coronary Intervention with Sirolimus-eluting Stent: Comparison of De Novo and In-stent Restenosis Lesions

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Background: The obesity paradox has been recently proposed in various heart disease treatments including percutaneous coronary intervention. However, no study has yet examined the effect of the obesity paradox on patients with diabetes mellitus (DM). Our aim was to evaluate the impact of body mass index (BMI) on the mid-term restenosis rate of sirolimus-eluting stent (SES) implantation in patients with and without DM. Furthermore, we evaluated the differences between de novo and in-stent restenosis lesions.

Methods: We evaluated 2,949 patients, 1211 (41.0%) of whom had had DM and had undergone SES implantation (excluding hemodialysis patients and hybrid stenting) between November 2002 and December 2008. The patients were classified as under/normal weight (BMI<25) and overweight (BMI≥25). We compared the restenosis rates with SES within 8 months between de novo and in-stent restenosis lesions based on BMI and the presence or absence of DM.

Results: Among patients with DM, the group of BMI≥25 (439 patients) had significantly reduced restenosis rate than that of BMI<25 (577 patients) in de novo lesions (BMI<25, 13.1%; BMI≥25, 7.8%; p=0.001), whereas no significant difference was present between the two BMI groups in in-stent restenosis lesions (BMI<25, 19.4%; BMI≥25, 16.5%; p=0.981). In contrast, among patients without DM, there was no significant difference in the restenosis rates between the two BMI groups in both de novo lesions (BMI<25, 6.1%; BMI≥25, 5.3%; p=0.433) and in-stent lesions (BMI<25, 14.6%; BMI≥25, 14.5%; p=0.535).

Conclusions: The obesity paradox was present only in restenosis after SES implantation for de novo lesions in patients with DM.

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Angiographic Features of Atherosclerotic Superficial Femoral Artery Disease in Diabetics and Non-diabetics Presenting with Claudication

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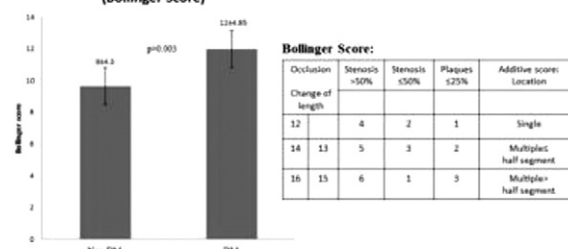
Background: Given lower durability of endovascular superficial femoral artery (SFA) revascularization in diabetics (DM) with claudication, we performed a comparative assessment of their angiographic disease in the SFA.

Methods: We conducted a blinded angiographic analysis of SFA disease in 112 consecutive patients (76 DM and 36 non-DM) referred for peripheral angiography for Rutherford category 3 claudication from Jan 2009 – Nov 2010.

Results: Significantly greater number of flow-limiting lesions (≥70% diameter stenosis) in DM were located in the distal SFA (71% vs. 22.2%, p=0.008) and popliteal artery (38% vs. 8.3%, p=0.004) compared to non-DM. Lesion length in DM was longer (DM: 138±73.3 mm vs. non-DM: 84±54.7 mm, p<0.001), with more grade 3 fluoroscopic calcification (50% vs. 8%; p=0.006) and more total occlusions (59% vs. 30.5%, p=0.02). Angiographic severity (Bollinger score) was higher in DM (12±4.85 vs. 9±4.3 p=0.003, Figure 1). Mean number of diseased (≥50% diameter stenosis) run-off vessels in DM and non-DM were 2.53 and 2.36, respectively (p=0.04). There was a greater need for bail-out stenting in DM compared to non-DM (93% vs. 33.5%; p<0.006) with longer stent lengths used in DM (241.5±98 mm vs. 195±116 mm, p<0.002). Atherectomy was more frequent in DM (72% vs. 10.7%; p<0.008). Overall, 12-month clinical patency rate was 63% in DM and 82% in non-DM (p<0.004).

Conclusions: DM with claudication have more severe angiographic SFA disease compared to non-DM, greater need for bail-out stenting and lower 12-month clinical patency, indicating the need for dedicated studies in DM.

Figure 1: Angiographic Severity of SFA Disease (Bollinger Score)



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Long-Term Outcomes of Biodegradable Polymer Drug-Eluting Stents versus Durable Polymer Sirolimus-Eluting Stents in Patients with Diabetes: A Pooled Analysis of Individual Patient Data from the ISAR-TEST 4 and LEADERS Randomized Trials

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Background: Patients with diabetes show higher rates of restenosis and stent thrombosis following PCI. Optimal for treatment of patients with diabetes is not known and no stent has demonstrated superior efficacy or safety. Late stent thrombosis is associated with impaired endothelial coverage and adverse vessel remodeling- both features of delayed arterial healing caused by permanent polymer drug-eluting stents (DES). Biodegradable polymer DES offer improved biocompatibility and may improved long-term outcomes.

Methods: We pooled individual patient data from 3 randomized clinical trials comparing biodegradable polymer DES with durable polymer DES (LEADERS, ISAR-TEST 4, ISAR-TEST 3). Clinical outcomes at 4-year from follow-up were assessed. The prespecified primary endpoint (MACE) comprised cardiac death, myocardial inf-arction, and target lesion revascularization (TLR). Secondary endpoints were TLR and definite or probable stent thrombosis.

Results: Of 1094 patients with diabetes, 657 received biodegradable polymer DES and 437 durable polymer DES. At 4 years, treatment with biodegradable DES versus durable polymer SES resulted in equivalent MACE (HR=0.95 [95%CI=0.74-1.21]; P=0.68) and TLR (HR=0.89[0.65-1.22]; P=0.46). Definite or probable stent thrombosis occurred less with biodegradable polymer DES (HR=0.52[0.28-0.96]; P=0.04). Landmark analysis showed less ST with biodegradable polymer DES between 1 and 4 years (HR=0.20[0.03-0.7]; P=0.02; Figure 1).

Conclusions: At 4-year follow-up polymer-free DES demonstrate improved long-term safety and equivalent efficacy when compared to durable polymer DES.

Definite or probable stent thrombosis